DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 4, 2014

Skeletal Kinetics® LLC
Ms. Christine Kuo,
Director, Regulatory Affairs and Quality Assurance
10201 Bubb Road
Cupertino, California 95014

Re: K132211
Trade/Device Name: SKaffold NMX
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 17, 2014
Received: July 18, 2014

Dear Ms. Kuo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(K) Number (if Known): K132211

Device Name: SKaffold NMX

Indications for Use:

SKaffold NMX is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. SKaffold NMX is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The device provides a bone void filler that resorbs and is replaced by bone during the healing process.

Prescription Use (Per 21 CFR 801 Subpart D)		AND/OR	Over-the-Counter Use (21CFR 801 Subpart C	
	X			

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132211

A COLSON ASSOCIATE

510(k) Summary

General Information as required by 21 CFR 807.92 (a) (1)

Submitters Name/Address: Skeletal Kinetics® LLC
10201 Bubb Road
Cupertino, CA 95014, USA

Date: August 4, 2014

Contact Person: Christine Kuo,
Director, Regulatory Affairs and Quality Assurance
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Device Name as required by 21 CFR 807.92 (a) (2)

Trade Name: SKaffold NMX
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV

Predicate Devices as required by 21 CFR 807.92 (a) (3)

The subject device is substantially equivalent in safety and effectiveness to the following legally marketed device (predicate) – Callos Bone Void Filler (K051123).

Device Description as required by 21 CFR 807.92 (a) (4)

SKaffold NMX is a pre-mixed moldable and biocompatible putty/paste bone void filler. SKaffold NMX consists of a mixture of calcium phosphate powder in a bioinert polyethylene glycol (PEG) based polymer that resorbs and is replaced with bone during the healing process. The 5 cc and 10 cc SKaffold NMX kits are provided sterile and are for single use only.

Intended Use as required by 21 CFR 807.92 (a) (5)

SKaffold NMX is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. SKaffold NMX is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Summary of Technological Characteristics as required by 21 CFR 807.92 (a) (6)

SKaffold NMX consists of moldable, biocompatible, resorbable calcium phosphate based material that can be applied directly to the intended sites. The polymer carrier used in SKaffold NMX is bioinert and biocompatible with host tissue and presents no new safety issues.

The intended use, and critical specifications (chemistry, crystallinity, physical form, porosity, and solubility) of SKaffold NMX are substantially equivalent to the predicate device, Callos Bone Void Filler (K051123).

Summary of Non-clinical Tests as required by 21 CFR 807.92 (b) (1)

Critical specifications (chemistry, crystallinity, physical form, porosity, and solubility) of SKaffold NMX were compared with those of Callos Bone Void Filler (K051123). Chemistry was determined by Fourier Transformed Infrared Spectroscopy (FTIR) and X-ray Diffraction (XRD) techniques. Crystallinity was determined by X-ray Diffraction. Physical form was determined by Scanning Electron Microscopy. Porosity was determined by Mercury Intrusion Porosimetry. Solubility was measured by *in vitro* dissolution method measuring Ca^{2+} ion concentration in solution using Inductively Coupled Plasma – Atomic Emission Spectroscopy. Performance test results demonstrated that SKaffold NMX has substantially equivalent critical specifications (chemistry, crystallinity, physical form, porosity, and solubility) as the predicate device Callos Bone Void Filler (K051123).

SKaffold NMX biocompatibility testing was performed in accordance with the standards set forth in ISO 10993-1, Biological Evaluation of Medical Devices and the test results demonstrated that SKaffold NMX met the requirements of the ISO standards.

In vivo, pre-clinical, large animal studies were performed in a cancellous bone defect model and showed gradual remodeling and replacement of implanted material by host bone. Histological, radiographic and histopathologic analyses were performed at 4 and 12 weeks that showed normal bone healing at the periphery of the cylindrical defects. No abnormal tissue responses were noted to the implanted device.

SKaffold NMX will be provided as a single use, sterile product. The radiation dose of 25kGy - 40 kGy will be validated in accordance with ISO 11137-2006, Sterilization of Health Care Products - Radiation to Sterility Assurance Level (SAL) 10^{-6}.

The results of risk management indicate that the identified hazards were acceptable and/or mitigated to an acceptable level with the residual risk evaluation deemed as acceptable per defined procedures.
Non-clinical animal data in a well defined rabbit model demonstrated that SKaffold NMX is resorbed over time and allows bone ingrowth as the device is resorbing.
SKaffold NMX maintains the previously demonstrated safety profile of the predicate device and is substantially equivalent to Callos Bone Void Filler (K051123).

Summary of Clinical Tests as required by 21 CFR 807.92 (b) (2)

SKaffold NMX does not require clinical test.

Conclusion as required by 21 CFR 807.92 (3)

The manufacturer compared the critical specifications - chemistry, crystallinity, physical form, porosity, dissolution/solubility of SKaffold NMX with the predicate device. The results indicated that the device characteristics for SKaffold NMX were the same as those of the predicate device. Therefore, SKaffold NMX bone void filler is substantially equivalent to the predicate device, Callos Bone Void Filler (K051123).